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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,907	07/25/2003	Mark Van Dyke	SwRI-2966-03	2421

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EXAMINER	
KOSAR, AARON J	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
08/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/626,907	VAN DYKE ET AL.	
	Examiner	Art Unit	
	AARON J. KOSAR	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-233* is/are pending in the application.

4a) Of the above claim(s) *34-220* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *221-233* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's amendment and argument filed May 6, 2008, in response to the non-final rejection, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Applicant has amended the claims by canceling claims 1-33 and introducing new claims 221-233. Claims 34-233 are pending. Claims 34-220 remain withdrawn pursuant to 37 CFR 1.142(b) as being drawn to non-elected species, there being no allowable generic or linking claim.

Claims 221-233 are pending and have been examined on the merits to the extent the claims are drawn/correspond to the elected invention and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 225 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is indefinite, because the term "coating comprises" is unclear. The term is unclear, because it is unclear if the claim is further descriptive of the keratin protein coating of claim 221 or if the term describes an alternate to the keratin coating. Each is a broad and reasonable interpretation of the claim though each embraces different subject matter such that one would not be apprised as to the composition(s) Applicant intends by the claims.

Please note, however, this ground of rejection may be overcome, for example, by amending claim 225 to recite the coating further comprises a bone morphogenic protein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Response to Arguments

Applicant has argued that the keratin-coated devices have unexpected results in the presence of osteoblasts. Applicant's arguments have been fully considered but, respectfully, they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (e.g., unexpected results, contact with osteoblasts) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With respect to the intended use as an orthopedic implant, a recitation of the intended use of the claimed invention must result in a *structural difference* between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Additionally, Applicant's reference to *Takeda v. Alphapharm* (herein referred to as Takeda) has been considered, however, found to be not persuasive. Takeda is drawn to a compound (a)

having the structure of pioglitazone including a specific cooperative arrangement of covalent bonds and atoms, wherein the structure is correlated to the function of the molecule having the claimed structure; (b) demonstrated to diverge from the activity and toxicity of *compound b*; and (c) wherein the use of the compound is taught away from in the prior art. Thus the reference and arguments to Takeda are not applicable to/not persuasive over the instant claims because, by contrast, the instant claims are drawn to a combination of elements minimally comprising titanium and keratin but lacking a structural-cooperative arrangement of the elements, for which the myriad of possible compositions/combinations are not correlated to - or provided a contextual reference point for - the myriad of potential "promoting" or "accelerating" activities of bone matrix formation.

Thus for the reasons of record and the reasons provided herein, the claims are rejected under 35 U.S.C. 103 (a).

Claims 221-224, 226-232 are rejected under 35 U.S.C. 103(a) as being unpatentable over KEN (US 20030004568 A1).

The claims are generally drawn to an orthopedic implant (composition) comprising a keratin-coated substrate. The dependent claims are further drawn to biocompatible substrates materials and bioactive factors, including the species of titanium and bone morphogenic protein (BMP).

KEN teaches a device comprising a polymer and bioactive agent coating the device formed of a biocompatible material. Ken also teaches the device comprises a biocompatible material, including titanium (¶ [0010]; claim 2); a polymer, including keratin (¶ [0013], claim 6); and, a bioactive agent, including a cell regeneration factor or a growth factor (¶ [0014], claim 7).

It would have been obvious to use the components of the instantly claimed combination (titanium/keratin(/growth factor)), because Ken teaches a combination of biocompatible material:polymer and because Ken teaches a finite number of representative components useful in the invention, selected from the species comprising titanium:keratin(:growth factor). One would have been motivated to combine the species because Ken teaches that each of the species is useful for each of the respective components that comprise the invention taught by Ken. Additionally, because the success of the invention is determined only insofar as the components must be contacted, one would have had a reasonable expectation of success in making the claimed composition, especially in the absence of evidence to the contrary.

To the extent that the claims are drawn to a medical device, including an orthopedic device/engineering construct as recited in the claims, the composition/device having the claimed structural elements/structural cooperative relationships is not limited to the intended use of the composition. In the absence of evidence as to the criticality of a particular combination or element(s) within each of the disclosed intended uses correlated to specific combinations, proportions, or other undisclosed features of the instantly claimed invention, then the minimal requirement of the presence of the components would be sufficient to satisfy any/all of the claimed uses. Thus the compositions taught by the teachings of Ken would be obvious over the instant claims whereby the similar compounds of the instant claims versus those of Ken differ not structurally, but in the recited/intended use.

Claims 221-232 are rejected under 35 U.S.C. 103(a) as being unpatentable over HAMMER (US 2003/0220700 A1) in view of VAN DYKE (US 6,371,984 B1) or SUITA-MANGANO (**Q1**:PTO/SB/08A, 2/24/2004: EP 0298684 A2).

The general teachings of the claims are above. The dependent claims additionally are drawn to bioactive factors, including the species bone morphogenic protein (BMP) and to the forms, species, and molecular weight of keratin.

HAMMER teaches a device/composition comprising a scaffold (part *#20*) and fixation component (part *#30*). Hammer also teaches that the #20 and #30 each comprising a limited number of known, representative species including titanium and the biopolymer, keratin, respectively (¶ [0029]). Hammer further teaches combining polymer with an active agent, including the growth factor BMP (¶ [0035), and a composition which can be blended with keratin, including growth factors, including bone morphogenic proteins (BMP) (¶ [0029], [0035]; figures).

VAN DYKE and SUITA-MANGANO teach that keratin may be obtained from a variety of tissues, including human hair (Van Dyke: column 2, ¶2; Suita-Mangano: page 2, ¶6, lines 34-43).

Although Hammer is silent regarding the specific combination titanium:keratin:BMP, it would have been obvious to make a titanium:keratin:BMP composition, because Hammer teaches a finite number of representative species comprising each of the individual components (titanium *or* keratin *or* polymers and blends (including keratin:BMP)), and because Hammer teaches that the compositions are useful for the same purpose (e.g. as scaffold components), it would be *prima facie* obvious to combine the elements so as to form the predictable composition

comprising titanium, keratin, *and* BMP in a composition useful for a scaffold/fixation component. To the extent the claims and the invention disclosed by prior art may differ by a recited molecular weight range, the claimed composition and the compositions made obvious by the prior art are determined to have a molecular weight of *about* 50-85kDa, especially in the absence of the criticality of molecular weight in the functioning of the composition or in the absence of objective evidence to the contrary which would preclude the compositions of the prior art from functioning to the extent instantly claimed.

Additionally, because the success of the invention is determinant insofar as the components must merely be contacted, one would have had a reasonable expectation of success in making the claimed composition, especially in the absence of evidence to the contrary.

To the extent that the instant claims are drawn to an orthopedic implant (device/composition) as recited in the claims, the composition/device is not limited to the intended use of the composition. In the absence of evidence as to the criticality of a particular combination or element(s) within each of the disclosed intended uses correlated to specific combinations, proportions, or other undisclosed features of the instantly claimed invention, then the minimal requirement of the presence of the components would be sufficient to satisfy any/all of the claimed uses. Thus the compositions of the instant claims whereby the similar compounds of the instant claims versus those of Hammer differ not structurally, but merely in the recited/intended use, would be obvious in view of the teachings of Hammer.

To the extent that the references are silent regarding the selection of a keratin species, the molecular weight properties, or the effect recited by the instant claims, it would have been obvious to one of skill to use keratin from a variety of sources, because keratin sources are well-

known as taught by SUITA-MANGANO and because VAN DYKE teaches that keratinous material may be obtained from a variety of sources for use in implantable devices, including keratinous material from human hair. Again, because the success of the composition (the "device") is dependent merely upon the ability of the contacting of the components especially in the absence of evidence to the criticality of a particular species of keratin source one would have had a reasonable expectation of success in combining the elements to include a keratin source including human hair in the device/composition.

It would have been obvious to use a keratin commensurate with the instantly claimed molecular weight range, because, although the cited art of HAMMER is silent regarding the recitation of a particular molecular weight of keratin, keratin would be expected to intrinsically comprise high-molecular weight keratin in the recited ranges. Furthermore, since the combination of elements of the device would have been obvious to one of skill, and because the coating effect appears to be dependent upon the combination of the elements, the combination of elements would thus be expected to intrinsically possess the claimed effect, especially in the absence of evidence to the contrary.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The rejection above, under 35 U.S.C. 103(a), being obvious over, in part, in view of VAN DYKE has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) to the extent it reads upon Van Dyke might be overcome (in part) with respect to the reference of Van Dyke by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome to the extent it reads upon the art of Van Dyke by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

No claims are allowed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

GODDARD (**AV1**: PTO/SB/08A, 2/24/2004) *teaches that keratin may be treated with oxidizing agents or reducing agents. Goddard also teaches that oxidizing agents are not specific to the keratin disulfide linkages, attack multiple domains in the keratin molecule, and act slowly; whereas reductants "act very quickly and without bringing about any appreciable chemical alteration than that concerned with the sulfur." Goddard also teaches the reductant sodium sulfide*

COOK (**U5**:PTO/SB/08A, 8/2008, Cook, S.D. et al "Hydroxyapatite-Coated Titanium for Orthopedic Implant Applications" Clinical Orthopaedics and Related Research. 1988, 232, pages 225-243.) *teaches the general benefit of coating titanium implants and coatings, including optimizing materials for tensile strength, corrosion-resistance, and biocompatibility.*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054.

The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Kosar
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651